

Application Number 10/698,291
Amendment in Response to Office Action mailed January 11, 2006

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REMARKS

This Amendment is responsive to the Final Office Action dated January 11, 2006, and the Advisory Action dated June 27, 2006. This Amendment accompanies a Request for Continued Examination (RCE) and supplements arguments submitted by Applicants in the After-final Response filed March 29, 2006. In this Amendment, Applicants have added new claims 60–63. Claims 1–63 are pending.

Applicant respectfully requests reconsideration in view of the arguments submitted in the After-final Response filed March 29, 2006, which are substantially reiterated below.

Response to Examiner's Arguments in Advisory Action

In the Advisory Action dated June 27, 2006, the Examiner stated that the application is not in condition for allowance because the term 'wire-like' in the claims "may comprise an elongated and pliable substance used for structural support and useable in a similar manner to that disclosed in the applied references." Applicants' claims require a fixation mechanism mounted to a lead body at a position between one of the electrodes and the proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site. Such a fixation mechanism is not taught by the applied references, as discussed in further detail below. Further, even if the term "wire-like" were read to encompass the anchor mechanisms taught by the applied references, Applicants' claims are still in condition for allowance because, as explained in detail below, none of the applied references teaches or suggests that the fixation mechanism including wire-like elements is mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body as recited by independent claims 1, 22, 42, and 53.

Claims 58 and 59

As a preliminary matter, Applicants note that in the Final Office Action, the Examiner addressed only claims 1–57, again apparently overlooking claims 58 and 59 of Applicants' application as originally filed. Applicants assume this is an oversight, and respectfully request that the Examiner consider and address claims 58 and 59 in the next communication.

Application Number 10/698,291

Amendment in Response to Office Action mailed January 11, 2006

Claim Rejection Under 35 U.S.C. § 102

In the Final Office Action, the Examiner rejected claims 1, 7-10, 22, 28-31, 42-51 and 53 under 35 U.S.C. 102(b) as being anticipated by Starkebaum (US Patent No. 5,733,322). Applicants respectfully traverse the rejection. Starkebaum fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. 102(b), and provides no teaching that would have suggested the desirability of modification to include such features. Applicants reiterate the remarks made in the Amendment dated October 19, 2005, and maintain all of the reasons for which the Examiner's rejections are improper.

In the Final Office Action, Examiner maintained the rejection of Applicants' claims 1, 7-10, 22, 28-31, 42-51 and 53 over Starkebaum, despite the fact that Starkebaum lacks any teaching or suggestion of several important elements of Applicants' claims. To summarize these deficiencies, Starkebaum fails to teach or suggest a lead including a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, as required by Applicants' independent claims 1, 22, 42, and 53. Further, Starkebaum fails to teach or suggest the lead body having a fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site, as further required by Applicants' independent claims 1, 22, 42, and 53. Applicants respectfully submit that the Examiner's rejection is improper and should be withdrawn.

The Examiner stated that Starkebaum at col. 1, lines 55-65, discloses a neurostimulation lead having a fixation mechanism including one or more expandable wire-like elements, mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body. Applicants can find no mention in the cited passage of wire-like elements, let alone wire-like elements mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body. Instead, referring to FIG. 1, the Starkebaum reference merely states: "To solve the problem of lateral lead migration of the electrodes 8 at distal end 6, protruding structure has been added to the distal end 6 of lead 2."¹ Adding a protruding structure to the distal end of a lead simply does not suggest adding wire-like elements to a position between one of the electrodes and the proximal end of the lead body.

¹ Starkebaum, col. 1, ll. 64-66, emphasis added.

Application Number 10/698,291

Amendment in Response to Office Action mailed January 11, 2006

FIG. 4B of the present application is shown below along with FIG. 8A of Starkebaum to aid the Examiner in understanding the fundamental differences between Applicant's claimed invention and the cited references. In each of the drawings shown below, the lead is shown oriented with the distal end at the left side of the Figure and the proximal end to the right side.

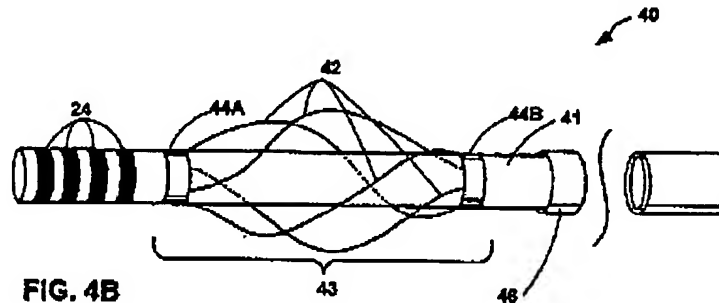


FIG. 4B

Claims 1, 22, 42, and 53 require that the fixation mechanism 43 of the neurostimulation lead 40 is mounted to the lead body at a position between one of the electrodes 24 and the proximal end of the lead body, as illustrated in FIG. 4B.

Quite the opposite, Starkebaum describes an extension 44 that “*extends distally beyond the most distal electrode 40 and becomes the distal end 36 of lead 32.*”²

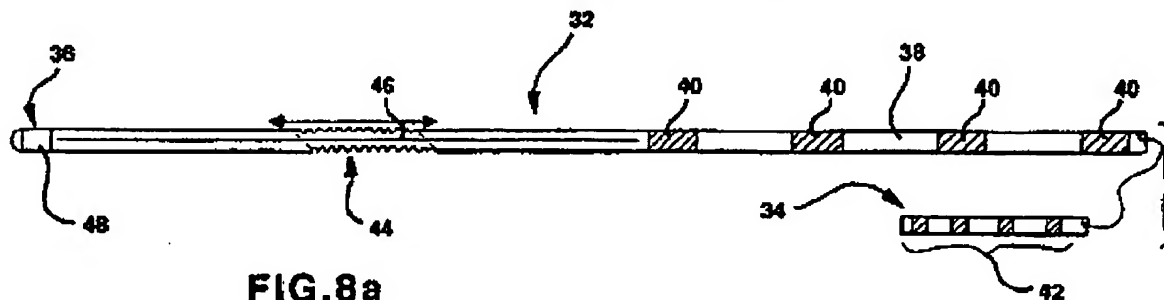


FIG. 8a

Moreover, Starkebaum contains no suggestion to modify its lead body to move the extension 44 to a location between an electrode and the proximal end of the lead body. In fact, Starkebaum suggests that the particular configuration shown is advantageous, because with the addition of a stop 24 sutured to the tissue outside the spinal column, “lead 32 is ‘anchored’ on both sides of electrodes 40 so there is a little chance of lead 32, and electrodes 40, migrating laterally or axially in epidural space 14.”³ It is therefore clear that Starkebaum fails to teach or suggest a fixation

² Starkebaum, col. 4, ll. 5–6, emphasis added.

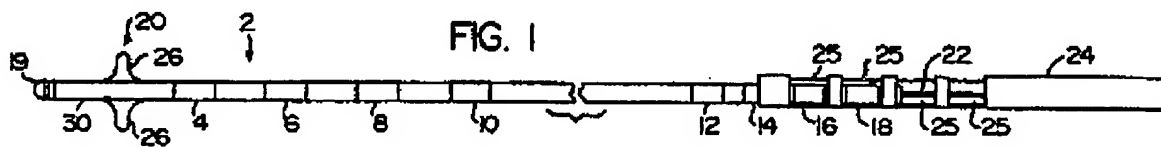
³ Starkebaum, col. 4, ll. 65–67.

Application Number 10/698,291

Amendment in Response to Office Action mailed January 11, 2006

mechanism mounted to a lead body at a position between one of the electrodes and the proximal end of the lead body, as required by independent claims 1, 22, 42, and 53.

Nor is this feature disclosed or suggested by Otten, a reference cited in a portion of Starkebaum relied on by the Examiner. Otten teaches an electrode catheter for providing drugs or electrical stimulation. Similar to the extension taught by the Starkebaum reference, the anchor mechanism 20 described by Otten is located between the distal end 19 and electrodes 4, 6, 8, and 10, as illustrated in FIG. 1 of Otten:



Moreover, neither Starkebaum nor Otten provides any teaching or suggestion of a fixation mechanism including one or more *wire-like elements* that are expandable to fix the lead body at a tissue target site. In contrast, Starkebaum merely suggests that its extension may include texturing in the form of dimples, ridges, or grooves. (Starkebaum, col. 5, ln. 19). Otten teaches that the anchor mechanism consists of a portion of the flexible tubular outer casing 30 of catheter 2, either formed into lobes by a plurality of longitudinal slits, or a continuous circular diaphragm. Otten describes that the flexible tubular outer casing and the anchor mechanism may be made of polyurethane, silicone rubber, or other biologically compatible polymer. (Otten, at col. 4, ll. 62–68. This does not provide any teaching of wire-like elements. Thus, Starkebaum and Otten fail to teach or suggest a fixation mechanism including one or more *wire-like elements* that are expandable to fix the lead body at a tissue target site, as required by Applicants' claims 1, 22, 42, 53.

In order to support an anticipation rejection under 35 U.S.C. 102(b), it is well established that a prior art reference must disclose each and every element of a claim. This well known rule

Application Number 10/698,291
Amendment in Response to Office Action mailed January 11, 2006

of law is commonly referred to as the "all-elements rule."⁴ If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. 102(b) is improper.⁵

In view of the fundamental differences identified above, Starkebaum falls far short of the requirements set forth in independent claims 1, 22, 42, and 53. Of course, the claims dependent on independent claims 1, 22, 42, and 53, i.e., claims 7-10, 28-31, and 43-51, incorporate all of the limitations of the respective base claims, and therefore are patentable for at least the reasons expressed above. Moreover, as explained in detail in Applicants' amendment dated October 19, 2005, dependent claims 7-10, 28-31, and 43-51 also include a number of other features not taught by Starkebaum.

Starkebaum fails to disclose each and every limitation set forth in claims 1, 7-10, 22, 28-31, 42-51 and 53. For at least these reasons, the Examiner has failed to establish a *prima facie* case for anticipation of Applicants' claims 1, 7-10, 22, 28-31, 42-51 and 53 under 35 U.S.C. 102(b). Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 103

In the Final Office Action, the Examiner rejected claims 4, 6, 12, 25, 27, 33 and 56 under 35 U.S.C. 103(a) as being unpatentable over Starkebaum in view of Sundquist et al. (US Patent No. 6,567,704). In addition, the Examiner rejected claims 2, 3, 5, 11, 23, 24, 26, 32, 52, 54, 55 and 57 under 35 U.S.C. 103(a) as being unpatentable over Starkebaum in view of Sundquist et al. The Examiner also rejected claims 13-19, 21 and 34-40 under 35 U.S.C. 103(a) as being unpatentable over Starkebaum in view of Barreras, Sr. et al (US Patent No. 6,192,279). In addition, the Examiner rejected claims 20 and 41 under as being unpatentable over Starkebaum in view of Racz et al. (US Patent No. 6, 146, 380).

Applicants respectfully traverse the rejections. The applied references fail to disclose or suggest the inventions defined by Applicants' claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention. Applicants reiterate

⁴ See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").

⁵ *Id.* See also *Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225 (CAFC 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).

Application Number 10/698,291

Amendment in Response to Office Action mailed January 11, 2006

the remarks made in the Amendment dated October 19, 2005, and maintain all of the reasons set forth therein for which the Examiner's objections are improper.

For example, neither Sundquist et al. nor Starkebaum teaches a fixation mechanism including wire-like elements configured in a substantial helical shape, as recited by claims 12 and 33. The Examiner stated that it would have been obvious to one of ordinary skill in the art to combine the teachings of Starkebaum with the resilient material found in Sundquist et al. to result in a fixation mechanism configured as wire-like elements in a substantial helical shape. However, the Examiner has identified no suggestion in the prior art of a motivation to combine the teachings of the applied references. Specifically, the Examiner has identified no motivation found within the prior art that teaches the modification of the anchoring extension of Starkebaum using the resilient flaps of the sealable member of Sundquist et al.

The Examiner has failed to explain why one of ordinary skill in the art would have looked to the resilient sealable member of Sundquist et al. for modification of the extension of Starkebaum for minimizing lead migration. The resilient sealable member described by Sundquist is designed to prevent ingress of bodily fluids such as blood into an inner lumen of a lead, and bears no relationship whatsoever to structures for lead fixation.

Moreover, even if the Starkebaum anchoring extension were modified by the teachings of Sundquist et al., such a modification would not result in Applicants' invention as claimed. At best, the suggested modification would result in an extension as disclosed by Starkebaum, made of a resilient material so as to maintain its original shape, located on the distal end of a lead. The modification would *not* achieve a fixation mechanism including wire-like elements, let alone wire-like elements configured in a substantial helical shape, as required by claims 12 and 33. Moreover, it is unclear how a resilient sealable member for preventing ingress of body fluids into a lead could have been considered relevant to a fixation mechanism.

As another example, the Examiner appears to have overlooked the features claimed in Applicants' dependent claims 3, 24, and 55, which recite a fixation mechanism including wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint. The Examiner failed to point to any teaching in the applied references that discloses or suggests this feature.

Application Number 10/698,291

Amendment in Response to Office Action mailed January 11, 2006

As explained above, neither Sundquist et al. nor Starkebaum teaches a fixation mechanism including wire-like elements; as such, these references certainly do not teach or suggest each of the wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint, as recited by claims 3, 24, and 55. Absent any showing of a prior art reference that teaches or suggests Applicants' claimed limitations, Applicants' claims 3, 24, and 55 should be allowed.

As a further example, neither Starkebaum nor Barreras, Sr. et al. teaches a fixation mechanism including wire-like elements, wherein one of the wire-like elements acts as an electrode for neurostimulation current, as recited by claims 14 and 35. In contrast, Starkebaum refers to the anchor mechanism of Otten (5,344,439), which consists of a plurality of lobes formed by a plurality of longitudinal slits in the flexible tubular outer casing of a catheter. The tubular outer casing described by Otten "may be of polyurethane, silicone rubber, or other biologically compatible polymer." (Otten, col. 4, ll. 64-68). The anchor mechanism material taught by Starkebaum via Otten is not a conductive material, and therefore cannot act as an electrode for neurostimulation current. Barreras, Sr. et al. similarly provides no teaching of a fixation mechanism including wire-like elements, one of which acts as an electrode. Neither do Starkebaum or Barreras, Sr. et al. provide any teaching that would have suggested the desirability of modification to arrive at this feature of claims 14 and 35.

Claims 2-6, 11-21, 23-27, 32-41, 52, and 54-57 are patentable for the same reasons stated above with respect to independent claims 1, 22, 42, and 53; namely, because the Starkebaum reference lacks the basic teachings attributed to it by the Examiner. Moreover, Sundquist et al., Barreras, Sr. et al, and Racz et al. provide no teaching sufficient to cure the basic deficiencies already evident in Starkebaum.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 2-6, 11-21, 23-27, 32-41, 52, and 54-57 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

Application Number 10/698,291
Amendment in Response to Office Action mailed January 11, 2006

New Claims

Applicants have added claims 60–64 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. As one example, the references fail to disclose or suggest the neurostimulation lead of claim 1, further comprising a plurality of retainer rings, wherein the retainer rings mount the wire-like elements to the lead body at proximal ends and distal ends of the wire-like elements, as recited by dependent claim 60. As another example, the references fail to disclose or suggest the neurostimulation lead of claim 1, wherein the fixation mechanism is spring-biased, as recited by dependent claim 61. As a further example, the references fail to disclose or suggest the neurostimulation system of claim 32, wherein the stylet provides an axial force that stretches the elastic portion of the lead body to restrain the wire-like elements against expansion, as recited by dependent claim 62. As yet another example, the references fail to disclose or suggest the neurostimulation system of claim 62, wherein the elastic portion of the lead body decreases in length upon removal of the stylet, as recited by dependent claim 63. No new matter has been added by the new claims.

CONCLUSION

All claims in this application are in condition for allowance. Applicants respectfully request reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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